MAR 2 1 2014

510(k) Summary

1 **Type of Submission:** Traditional

2 **Orginal Submission Date:** 2013/11/29

3 **Submitter:** Yung Sheng Optical Co., Ltd.
Address: 3F-1, No.6, Jhongke Road, Daya District, Taichung City 42881 Taiwan
Manufacturer Address No.8, Keya 2nd Road, Daya District, Taichung City 42881, Taiwan
Phone: +886-4-25658384 #156
Fax: +886-4-25658387
Contact: Wen-Han Chen
Establishment Registration Number: N/A

4 **Identification of the Device:**

Proprietary/Trade name:	Eye Secret 55 UV Aspheric (methafilcon A) Soft (hydrophilic) Contact Lens
Common Name:	Contact Lens
Classification Name:	Soft (Hydrophilic) Contact Lens (daily wear)
Device Classification:	II
Regulation Number:	886.5925
Panel:	Ophthalmic
Product Code:	LPL
Subsequent Product Code:	MVN

5 **Identification of the Predicate Device:**

Predicate Device Name:	SAUFLON 55 UV (methafilcon A) Soft (Hydrophilic) Visibility Tinted Contact Lens for Daily Wear
Manufacturer:	Sauflon Pharmaceuticals Ltd.
510(k) Number:	K013649

6 Intended Use and Indications for Use of the subject device.

The Eye Secret 55 UV Aspheric (Methafilcon A) Soft (Hydrophilic) Contact lenses are indicated for the correction of ametropia (myopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from 0.00 to -12.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.
Eye Care professionals may prescribe the lens for daily disposable or daily wear in a Frequent Replacement Program. As prescribed for planned replacement, the lens should be disinfected using a chemical or hydrogen peroxide disinfecting systems.

7 Device Description

The Eye Secret 55 UV Aspheric (methafilcon A) Soft (hydrophilic) contact lens is manufactured by using advanced cast molding method. The lens material, methafilcon A, is a random copolymer of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid (MAA) crosslinked with ethylene glycol dimethacrylate (EGDMA). A UV absorbing monomer is used to block UV radiation. The average transmittance characteristics are less than 5% in the UVB range of 280~315 nm and less than 50% in the UVA range of 316 to 380 nm. The lenses are tinted blue for visibility purposes with the color additives, C.I. Reactive Blue No.4. The Lenses are available as aspheric lenses.

8 Summary of Clinical Study

Methafilcon A lenses have been used widely. Its safety and effectiveness have been well documented. Their safety and effectiveness can be further exemplified by the lenses cleared by FDA.

SAUFLON 55 UV (Methafilcon A) Soft (Hydrophilic) Visibility Tinted Contact Lens for Daily Wear. K013649 submitted by Sauflon Pharmaceuticals Ltd.

Clinical study for Eye Secret 55 UV Aspheric (Methafilcon A) Soft (Hydrophilic) Contact Lens is not required for the premarket notification as the USAN name and process are the same as above mentioned predicated device.

9 Non-clinical Testing

A series of preclinical testing were performed to demonstrate the safety and effectiveness of the Eye Secret 55 UV Aspheric (methafilcon A) Soft (hydrophilic) contact lens. The results of all testing demonstrated that the safety and effectiveness of the Eye Secret 55 UV Aspheric (methafilcon A) Soft (hydrophilic) contact lens are equivalent to the SAUFLON 55 UV (methafilcon A) Soft (Hydrophilic) Visibility Tinted Contact Lens for Daily Wear (K013649). The following tests were conducted as recommended by the FDA Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses, February 27, 1997:

- Toxicity
    1. Acute Systemic Injection Study: The lens material meets the requirements of the systemic injection test and is considered non-toxic.
    2. White Rabbit Ocular Irritation Test: Ocular irritation test was performed and produced no ocular irritation.
    3. Cytotoxicity Test: The test article meets the requirements of ISO 10993-5.
- Extractables (Leachability)
- Finished Lens Parameters
- Light Transmittance
- Refractive Index
- Water Content
- Oxygen Permeability
- pH and Osmolality Test
- Shelf-life
- Mechanical Comparative Testing

In addition to biocompatible tests, shelf-life, physical compatibility test of contact lens care solution, mechanical comparative testing and the comparative tests of the performance tests mentioned above are provided.

The results of the non-clinical testing demonstrate that the Eye Secret 55 UV Aspheric (methafilcon A) Soft (hydrophilic) contact lens is substantially equivalent to the predicate devices.

10 Substantial Equivalence Determination

The Eye Secret 55 UV Aspheric (methafilcon A) Soft (hydrophilic) contact lens submitted in

this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared SAUFLON 55 UV (methafilcon A) Soft (Hydrophilic) Visibility Tinted Contact Lens for Daily Wear which is the subject of K013649. Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

Item	Eye Secret 55 UV Aspheric (methafilcon A) Soft (hydrophilic) contact lens	Predicate Device (K013649) SAUFLON 55 UV (methafilcon A) Soft (Hydrophilic) Visibility Tinted Contact Lens for Daily Wear
Regulatory Number	886.5925	886.5925
Classification	II	II
Intended Use	The Eye Secret 55 UV Aspheric (Methafilcon A) Soft (Hydrophilic) Contact lenses are indicated for the correction of ametropia (myopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from 0.00 to -12.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. Eye Care professionals may prescribe the lens for daily disposable or daily wear in a Frequent Replacement Program. As prescribed for planned replacement, the lens should be disinfected using a chemical or hydrogen peroxide disinfecting systems.	The Sauflon 55 UV soft (hydrophilic) contact lens is indicated for daily wear for the correction of the refractive ametropia (myopia and hyperopia) and astigmatism in aphakic and not-aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 Dioptres that does not interfere with visual acuity. Eyecare Practitioners may prescribe the lens for daily wear in a Frequent Replacement Program. The lenses may be disinfected using chemical or hydrogen peroxide disinfection systems.
Prescription Use	Yes	Yes
Material	Methafilcon A	Methafilcon A
Manufacturing Method	Cast Molded	Cast Molded
Water Content	55%	55%
Dk	22.0 x 10^{-11} (cm^2/sec) (mlO_2/ml x mmHg)	22.0 x 10^{-11} (cm^2/sec) (mlO_2/ml x mmHg)
Powers	0 ~ -12.00 D	± 20.00D
Light Transmittance	95% ± 5%	94.61%
UV-A	< 50%	36.00%

UV-B	< 5%	9.41%
Refractive Index	1.409	1.402
Base Curve	8.4 mm ~ 8.8 mm	8.40mm ~ 9.30mm
Diameter	14.0 mm ~ 14.4 mm	14.0mm ~ 15.0mm
Tint	C.I. Reactive Blue #4	Reactive Blue No. 4

11 Conclusion

After analyzing bench tests, safety testing data, it can be concluded that Eye Secret 55 UV Aspheric (methafilcon A) Soft (hydrophilic) contact lens is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

March 21, 2014

Mr. Wen-Han Chen,
Director of Regulatory Affairs Division
Yung Sheng Optical Co.,
3F-1, NO. 6, Jhongke Road, Daya District,
Taichung City 42881, Taiwan

Re: K133735
Trade/Device Name: Eye Secret 55 UV Aspheric (methafilcon A) Soft (hydrophilic) Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: December 23, 2013
Received: December 27, 2013

Dear Mr. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: Registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled,"Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133735

Device Name
he Eye Secret 55 UV Aspheric (Methafilcon A) Soft (Hydrophilic) Contact lenses

Indications for Use *(Describe)*
The Eye Secret 55 UV Aspheric (Methafilcon A) Soft (Hydrophilic) Contact lenses are indicated for the correction of ametropia (myopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from 0.00 to -12.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.
Eye Care professionals may prescribe the lens for daily disposable or daily wear in a Frequent Replacement Program. As prescribed for planned replacement, the lens should be disinfected using a chemical or hydrogen peroxide disinfecting systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Leonid Livshitz -S
2014.02.19 10:14:43 -05'00'

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